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| PPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------------|----------------------|---------------------|------------------|
| 09/830,894 | 04/27/2001 | Lu-Kwang Ju | 5277 | 5277 |
| 39905 | 7590 02/15/2006 | | EXAMINER | |
| ROETZEL AND ANDRESS | | | MARX, IRENE | |
| 222 SOUTH AKRON, O | IAIN STREET 44308 | | ART UNIT | PAPER NUMBER |
| maton, o | | | 1651 | |
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DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|
| | 09/830,894 | JU, LU-KWANG | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Irene Marx | 1651 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timulated and will expire SIX (6) MONTHS from a cause the application to become ABANDONE! | I. lely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 30 De | <u>ecember 2005</u> . | | | | | |
| , | ,— | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 3 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-4,10,16-19,21,28,31-34,70,106-108</u> 4a) Of the above claim(s) is/are withdraw 5)□ Claim(s) is/are allowed. 6)⊠ Claim(s) <u>1-4,10,16-19,21,28,31-34,70,106-108</u> | vn from consideration. | e application. | | | | |
| 7) Claim(s) is/are objected to. | <u>, 111 and 112</u> israte rejected. | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine | r | | | | | |
| 10) The drawing(s) filed on is/are: a) acce | | Examiner. | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Ex | ion is required if the drawing(s) is obj | ected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of | s have been received. s have been received in Application rity documents have been receive (PCT Rule 17.2(a)). | on No ed in this National Stage | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary Paper No(s)/Mail Da | | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | | atent Application (PTO-152) | | | | |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/30/05 has been entered.

Claims 1-4, 10, 16-19, 21, 28, 31-34, 70, 106-108 and 111-112 are being considered on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 10, 16-19, 21, 28, 31-34, 70, 106-107 and 111 are rejected under 35 U.S.C. 102(b) as being anticipated by Robertson *et al.* (Appl. Environ. Microbiol., 1988. Vol. 54, pages 2812-2818) in light of Brock.

The claims are directed to a process of making a biological product with a microorganism including bacteria, yeasts, molds and archaea in a medium containing an alternative oxidant source and under anaerobic conditions such that at least a portion of the population consumes said alternative oxidant at least a portion of the production process.

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Robertson *et al.* disclose a process of making a biological product with *T. pantotropha* wherein if the oxygen within the culture medium is less than the maximum rate of oxygen replenishment to the culture medium, the microorganisms will substantially utilize oxygen for cellular respiration, and when the oxygen requirements for cellular respiration of the strain within the culture medium is greater than the maximum rate of oxygen supply to the culture medium, then at least a portion of the microorganism concentration within the culture medium will utilize the alternative oxidant source for cellular respiration during at least a part of the production process. See, e.g., page 2814. The electron acceptors are oxygen, nitrate and/or nitrite. See, e.g., Table 3. The strain has the ability to produce biopolymers such as proteins, including enzymes and other cellular components, including biosurfactants such as fatty acids and other lipids. The plasma membrane of bacteria contains lipids and fatty acids, including phospholipids, which are biosurfactants (See, e.g., pages 21-32).

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant now argues that the biomass of Robertson may contain proteins, but that they are not specifically indicated to be enzymes. In this regard, applicant fails to consider that proteins are, in fact, biopolymers, as are other components of biomass, such as fatty acids, lipids, polysaccharides, and, of course, enzymes, even if they are not specifically recited. See, e.g., Table 2, page 2814. In addition, as noted *supra*, bacteria, comprise biopolymers, enzymes and biosurfactants. All living cells are bounded by a plasma membrane that contains lipids and fatty acids, including phospholipids, which are biosurfactants. In addition, bacteria contain various proteins, including enzymes and other biomolecules required for their metabolic functions, such as enzymatic degradation of food for growth and proliferation (See, e.g., pages 21-32).

Claims 1-4, 6-34, 70 and 105-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson *et al.* taken with Wendt *et al.* (U.S. Patent No. 3,939,068), Brock and Wagner *et al.* (U.S. Patent No. 4,814.272) for the reasons as stated in the last Office action and the further reasons below.

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The claims are directed to a process of making a biological product which is at least a biosurfactant, biopolymer or enzyme with a microorganism including bacteria, yeasts, molds and archaea in a medium containing an alternative oxidant and under anaerobic conditions at least a portion of the population consumes said alternative oxidant at least a part of the production process.

Robertson is discussed supra.

The reference differs from the claimed invention in that it does not indicate the biological products produced by *Pseudomonas* strains or the precise process parameters. However, the reference does suggest that *Pseudomonas* has similar capabilities of growing and producing biological products under aerobic and anaerobic conditions as the strain of Robertson *et al.*, since it is capable of nitrification. See, e.g., Table 4, page 2817.

In addition, Wendt *et al.* disclose a process for the production of a biological product with cells of a microorganism including *Pseudomonas* (col. 4, lines 58-64) under aerobic and anaerobic conditions in the presence of alternative oxidant sources such as nitrates such that the strain uses the alternative oxidant source when the demand of oxygen exceeds the supply. See, e.g., col. 6, lines 27-60.

The reference differs from the claimed invention in that nitrate is the only oxidant or electron acceptor disclosed for anaerobic respiration. However, Brock discloses a variety of such oxidants, including fumarate, sulfate, sulfur, ferric ion and nitrite (See, e.g., pages 113-114).

The substitution of nitrate or another ion with of salts or acids as the source of the respective ion is deemed to be well within the ordinary skill in the art, particularly since the respective ions are generally provided as a salt in an aqueous nutrient medium environment.

The references further differ from the invention as claimed in the use of small acids or fatty acids in the medium and in the specific production of a biosurfactant. However, Wagner et al. adequately demonstrate that it is routine in the art to provide nutrient media containing small acids, such as malonate, succinate, pyruvate or malate, or fatty acids such as stearic acid for microorganisms, including *Pseudomonas*. (See, e.g., col. 3) for the production of a biosurfactant such as a rhamnolipid. The Wagner et al. reference also addresses the use of nutrient limitation in the cultivation of bacteria, specifically by limiting magnesium or nitrogen for the production of rhamnolipids with *Pseudomonas* (See, e.g., Examples 2-3).

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One of ordinary skill in the art would have had a reasonable expectation of success in obtaining a biological product by cultivation of a microorganism in the presence of an alternative oxidant source under aerobic conditions followed by anaerobic conditions using a variety of carbon sources and the limitation of a variety of nutrients to boost yields of various biological products including at least a biosurfactant, biopolymer or enzyme depending on the specific microorganism to be cultured and/or the product to be produced.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of cultivation of Robertson *et al.* by using *Pseudomonas* strains as taught by Wendt *et al.* and further by the substitution of nitrate by other oxidants, as suggested by Brock, when the oxygen demand exceeds the oxygen supply, as well as the use of nutrient limitation and various carbon substrates, as suggested by the teachings of Wagner *et al.* for the expected benefit of maximizing the production of useful biological products produced by a microorganism such as rhamnolipids suitable for use in the pharmaceutical industries and for foods or feed, for example.

Thus, the claimed invention as a whole was clearly <u>prima facie</u> obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The only arguments provided is that none of the secondary art cures the deficiencies in Robertson *et al.*. Inasmuch as the alleged deficiencies in Robertson *et al.* have been addressed *supra*, it is submitted that applicant has not overcome the strong *prima facie* case of obviousness made out over the references.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner

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